607 HFI-35 7/11/97

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
4298 Elysian Fields Avenue
New Orleans, LA 70122-3848
Telephone (504) 589-7166
Fax (504) 589-4657

July 2, 1997

WARNING LETTER NO. 97- NOL-52

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Nouri E. Hakim
President
Contract Manufacturing, Inc.
P.O. Box 4963
Monroe, LA 71211

Dear Mr. Hakim:

During an inspection of your firm located at 2813 DeSiard Street, Monroe, Louisiana, our investigator determined that your firm manufactures teethers (a Class II device). Teethers are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or the controls used for, manufacturing, packing, storage, or installation are not in compliance with the Good Manufacturing Practice (GMP) regulations for medical devices, as specified in Title 21, *Code of Federal Regulation* (CFR), Part 820, as follows:

(1) failure to completely review and approve Device History Records;

(2) failure to validate manufacturing processes (UV light used to sanitize the water, and radio frequency welding process used to seal the teethers);

(3) failure to follow Quality Control (QC) testing procedure;

(4) failure to document calibration of equipment;

(5) failure to document label review before use.

The teethers are misbranded under Section 502(o) of the Act because notices or other information respecting the device was not provided to the Food and Drug Administration prior to their introduction into interstate commerce as required by Section 510(k) of the Act.

The teethers also are adulterated under Section 501(f)(1)(B) in that they are Class III devices under Section 513(f)(1), since you do not have premarket approval in effect pursuant to Section 515(a)(2), or an approved application for an investigational device exemption under 520(g). In order to obtain further information regarding the requirements for a 510(k) premarket notification, you have the option of contacting the Division of Small Business Manufacturers Assistance, 800-638-2041 and/or accessing the guidance provided on the Internet at HTTP://www.fda.gov/CDRH/manual/510kprt1.html.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Carolyn S. Olsen, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3848, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Olsen.

Sincerely,

Martin Goldstein

James E. Gamet
acting District Director
New Orleans District

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Enclosure: FDA-483

cc: Mr. Joseph H. Hakim
Vice-President
Contract Manufacturing, Inc.
2813 DeSiard Street
Monroe, LA 71201